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Original Research

Investigating the Relationship Between Insulin Treatment Refusal and Psychosocial Factors in Type 2 Diabetic Patients

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ABSTRACT

Objective: Refusal of insulin therapy is an important barrier in the treatment of type 2 diabetes mellitus (T2DM). The current study aimed to investigate the effect of psychosocial status of diabetic patients on insulin treatment acceptance and refusal.

Methods: This cross-sectional study was conducted with age and gender matched 80 diabetic patients who accepted insulin therapy and 80 diabetic patients who refused insulin therapy. Participants were interviewed face-to-face using a questionnaire consisting of five sections: socio-demographic, depression, anxiety, fear of self-injection and adherence to diabetes treatment.

Results: There was no significant difference between the two groups in terms of age and gender. The beck depression scale score *(p=0.002)* and beck anxiety scale score *(p<0.001)* of the participants who refused insulin treatment were statistically significantly higher than the group who accepted the treatment. The injection fear scale score of the group who refused insulin treatment was statistically significantly higher than those who accepted insulin treatment *(p<0.001)*. There was a significant negative correlation between injection fear score and treatment adherence scale score in both participants who accepted *(r:-0.224; p:0.045)* and refused insulin treatment *(r:-0.309; p:0.005)*.

Conclusion: The current study showed that depressive and anxiety moods of the individuals caused insulin therapy refusal. In addition, fear of injection was another factor causing insulin treatment refusal. Depression and fear of injection were also found to negatively affect adherence to treatment.

Keywords: Diabetes mellitus; insulin; medication adherence; treatment refusal

INTRODUCTION

Diabetes Mellitus (DM) is recognized as the third leading cause of death worldwide and is becoming a major public health problem. The International Diabetes Federation (IDF) stated that 425 million adults were living with DM in 2015, with an estimated worldwide prevalence of 9.1%, which is projected to increase to 693 million by 2045 [1]. In Turkey, the prevalence of type 2 DM is estimated at 13.7%, making it the most prevalent country in the European region [2].

Poor blood glucose management can result in a number of illnesses, including cardiovascular disorders, which account for the majority of morbidity and death among diabetics. Additionally, it is to blame for the increased direct and indirect medical costs incurred by DM patients [3]. Numerous pharmacologic options are widely available for the treatment of diabetes. While oral antidiabetic agents are commonly the first choice, as diabetes is a progressive disease and oral hypoglycemic agents (OHAs) eventually lose their effectiveness, a large proportion of people with diabetes will eventually need to switch to insulin therapy, either alone or in combination with OHAs. Insulin therapy is still considered the most effective pharmacologic option for the treatment of diabetes [4].

To prevent and reduce long-term diabetes complications, early use of insulin is recommended in the treatment of poorly controlled diabetes. Patients who start insulin therapy early are less likely to experience chronic hyperglycemia, which lowers their chance of developing complications from diabetes. Even yet, it's typical to start insulin later than expected [5]. About half of patients with poorly managed type 2 diabetes did not begin insulin therapy at the appropriate time; insulin therapy is typically started three to five years after oral hypoglycemic medications have failed [5]. Another study reported that first insulin use was delayed by an average of 10.3 years and that the mean A1c at insulin initiation was 9.0% [6]. Xiong et al. [7] reported that 800 (17.9%) of patients who were recommended to use insulin did not want to start treatment due to reasons such as discomfort, dependence concerns, pain, high cost and possible side effects. Gherman et al. [8] as a result of the literature review, they reported that the barriers to insulin acceptance were categorized into 4 main groups. Refusal to take insulin or reduced adherence to insulin therapy can be caused by a variety of emotional and cognitive factors, including fear of needle stick pain, fear of self-injection, fear of injection technique or correct dosing, and fear of the negative effects of using insulin, such as hypoglycemia, weight gain, lifestyle restriction, and discomfort; social and cultural factors and relational factors, such as social stigma and shame, social stigma and embarrassment, social stigma and embarrassment, and embarrassment; and physical factors, such as pain or bruises from injections. Due to the complexity of non-adherence to insulin therapy, factors associated with non-adherence to insulin therapy are often explored in very specific contexts and therefore often include only a few factors.

Main Points;

- Diabetic participants who refused insulin treatment had higher depression scores.
- Diabetic participants with high anxiety scores were more likely refused insulin treatment.
- Fear of injection is an important reason for insulin treatment refusal.
- Depression, anxiety, and fear of injections negatively affected diabetes mellitus treatment adherence.

"Psychological insulin resistance" (PIR) is a person's opposition to insulin use. Sociodemographic, individual and environmental characteristics have been reported to cause PIR. Psychological insulin resistance is not a formal psychological diagnosis, but rather a term that captures a strong negative attitude towards starting insulin therapy [9]. What is known about the relationship between psychosocial factors affecting the individual and acceptance of insulin therapy is limited. Previous studies have reported that depression decreases acceptance of insulin therapy.[5] Despite all these literature data, studies examining the psychosocial status of patients who refuse insulin therapy are limited and new studies are needed.

The current study aimed to investigate the reasons for refusal of insulin treatment in patients who were indicated for insulin treatment by a physician but refused to start insulin treatment.

MATERIALS AND METHODS

This cross-sectional study was conducted between July 1, 2022 and March 31, 2023 in the endocrinology clinic of a tertiary health care institution. In our endocrinology clinic, health care is provided to all diabetic patients who are referred from primary and secondary healthcare institutions and who apply directly. The population of the study consisted of all T2DM patients admitted to the endocrinology clinic. The depression scores (5.11±0.24 and 6.20±0.35) obtained in the study conducted by Onalan et al. [10] were used to calculate the sample size. In the light of the data obtained from the previous study, it was determined that at least 80 people in each group should be included in the study with power=0.95 (beta=0.05), alpha=0.05 and effect size (d=0.3) in the student t test based Power analysis test (G-power 3.1 package programe). Type 1 DM, those with a diagnosis of psychological illness (depression, anxiety disorder, etc.), those with chronic neurological diseases, and those with visual and auditory problems that would prevent communication were

excluded from this study. A total of 163 volunteer participants over the age of 18 years and diagnosed with T2DM who accepted insulin treatment or refused insulin treatment were randomly included in the study.

Data Collection

Data were collected using a structured questionnaire administered by the researcher. The questionnaire consisted of five sections: the first part (part I) was used to collect sociodemographic characteristics, part II was used to collect adherence to insulin therapy (Morisky 8-item Medication Adherence Questionnaire), part III was used to assess subjects' depressed mood (Beck Depression Scale), Part IV was used to assess subjects' anxiety mood (Beck Anxiety Scale), and Part V was used to assess participants' fear of the disease and insulin treatment (Fear of Self-Injection and Testing Questionnaire).

Patients' adherence to their diabetic treatment was assessed using the 8-item modified Morisky adherence scale (MMAS-8). The eight items of the validated MMAS-8 self-report measure of adherence are part of the tool. Items 1 through 7 featured a "yes" or "no" response option, while question 8 featured a 5-point Likert scale. With the exception of item 5 (reversed score), where the responses "yes" and "no" were rated as "1" and "0," respectively, every "no" response was scored as "1" and every "yes" response as "0". The difficulty remembering to take insulin therapy was measured on item 8 using 5-point Likert scales: never/rarely = 0, once in a while = 1, occasionally = 2, generally = 3, and always = 4. In this scale, if patients choose response "0", the score is "1" and if they choose response "1,2,3, or 4", the score is "0". Higher scores indicate higher adherence levels. The total scores of all the items range from 0 to 8 and was grouped into two levels: adherent (score of 6 to 8), and non-adherent (score < 6). A total score of 8 indicates high adherence, 6-7 points indicate moderate adherence, and <6 points indicate low adherence [11].

The Turkish version of the Beck Depression Scale was used to ask the subjects about their depressive traits. There are a total of 21 items on the Likert-type scale. Every item has a score that ranges from 0 to 3. The scale's total score ranges from 0 to 63. The more depressed one feels, the higher their score on the scale [12].

The Turkish version of the Beck Anxiety Scale was used to ask the subjects about their anxiety traits. There are 21 items on this Likert-style self-assessment scale, with scores ranging from 0 to 3. A high overall score denotes a high degree of anxiety that the individual is experiencing. The internal consistency of the BAI is high (alpha = 0.93) [13].

Participants' fear of self-injection and self-testing during diabetes treatment was assessed with the Turkish Version of the Diabetes Fear of Self-injecting and Self-testing Questionnaire (D-FISQ). The D-FISQ, which contains a total of 15 statements, consists of two subscales: fear of self-injection (fear of self-injection-FSI, 6 statements) and fear of self-testing (fear of self-testing-FST, 9 statements). Each statement has a four-point Likert-type scale ranging from 0 to 3 (0= almost never, 1= sometimes, 2= often, 3= almost always). Self-injection fear score ranges from 0-18, self-test fear score ranges from 0-27 and total fear score ranges from 0-45. An increase in score indicates an increase in fear. Item-total correlation coefficient ranged from 0.72 to 0.86. In terms of test-retest reliability, intraclass correlation coefficient was reported to be over 0.90 [14].

Statistical Analysis

The data was statistically analyzed using the IBM SPSS (statistics Package for Social Sciences) 22 statistics package application. To ascertain if the continuous data were normally distributed, the Shapiro-Wilk test was employed. For continuously distributed variables, the descriptive statistics were represented as mean ± standard deviation; for non-normally distributed variables, as [median (min-max)]; and for categorical variables, as frequency and percentage [n(%)]. Pearson Utilizing the Fischer Exact and Chi-Square tests, the association between category data was investigated. For continuous data that did not fit the normal distribution, the Mann-Whitney-U test was used to examine the association between two independent groups; the Kruskal Wallis test was employed to compare more than two independent groups; and the Dunn test was utilized as a post Hoc test. Spearman correlation analysis was used to analyze the relationship between two continuous variables. The significance level was set as $p<0.05$.

RESULTS

The study included 80 (50.0%) participants who accepted insulin treatment and 80 (50.0%) who refused insulin treatment. Participants who refused insulin treatment had a statistically significantly higher history of hospitalization in the last 1 year (Table 1).

Table 1. Comparison of sociodemographic characteristics of the participants

Variables	Accept insulin n (%)	Refusing insulin n (%)	Total n (%)	p
Gender				
Female	40 (50.0)	43 (53.8)	83 (51.9)	0.635
Male	40 (50.0)	37(46.2)	77 (48.1)	
Marital status				
Married	68 (85)	60 (75)	128 (80)	0.247
Single	2 (2.5)	2 (2.5)	4 (2.5)	
Widow or divorced	10 (12.5)	18 (22.5)	28 (17.5)	
Educational level				
Illiteraate	16 (20.0)	20 (25.0)	36 (22.5)	
Literate	18 (22.5)	14 (17.5)	32 (20.0)	0.097
Primary school	20 (25.0)	30 (37.5)	50 (31.3)	
High school	22 (27.5)	10 (12.5)	32 (20.0)	
University	4 (5.0)	6 (7.5)	10 (6.3)	
Profession				
Housewife	36 (45.0)	38 (47.5)	74 (46.3)	
Officer	21 (26.3)	30 (37.5)	51 (31.9)	0.134
Minimum wage employee	9 (11.3)	3 (3.8)	12 (7.5)	
Tradesmen	11 (13.8)	5 (6.3)	16 (10.0)	
Retired	3 (3.8)	4 (5.0)	7 (4.4)	
Smoking				
Yes	21 (26.3)	18 (22.5)	39 (24.4)	0.581
No	59 (73.8)	62 (77.5)	121 (75.6)	
Alcohol use				
Yes	2 (2.5)	1 (1.3)	3 (1.9)	>0.999
No	78 (97.5)	79 (98.8)	157 (98.1)	
Death of a relative in the last 6 months				
Yes	10 (12.5)	13 (16.3)	23 (14.4)	0.499
No	70 (87.5)	67 (83.8)	127 (85.6)	
Follow-up and treatment feature				
I take my medication regularly. I do not neglect my follow-ups	56 (70.0)	47 (58.8)	103 (64.4)	
I sometimes neglect my treatment and follow-ups	24 (30.0)	31 (38.8)	55 (34.4)	0.168
I only take my medication and go to the doctor when I have complaints	0 (0.0)	2 (2.5)	2 (1.3)	
Chronic disease status				
Yes	62 (77.5)	62 (77.5)	124 (77.5)	>0.999
No	18 (22.5)	18 (22.5)	36 (22.5)	
Hospitalisation in the last 1 year				
Yes	24 (30.0)	40 (50.0)	64 (40.0)	***0.010***
No	56 (70.0)	40 (50.0)	96(60.0)	

There was no significant statistical difference between the median values of age of the participants who accepted and refused insulin treatment *(p=0.152)*. The median values of fasting blood glucose *(p<0.001)* and HbA1c *(p<0.001)* were statistically significantly higher in the participants who refused insulin treatment than in the group who accepted insulin treatment (Table 2).

The beck depression scale *(p=0.002)* score and beck anxiety scale score *(p<0.001)* of the participants who refused insulin treatment were statistically significantly higher than the group who accepted the treatment. The injection fear scale score of the group who refused insulin treatment was statistically significantly higher than those who accepted insulin treatment *(p<0.001)*. There was no significant difference between the treatment compliance scale scores of the two groups *(p=0.119)* (Table 3).

There was a significant negative correlation between injection fear score and treatment adherence scale score in both participants who accepted *(r:-0.224; p:0.045)* and refused insulin treatment *(r:-0.309; p:0.005)*. There was a negative significant correlation between the depression score of the participants who refused insulin treatment and the treatment compliance score (Table 4).

Table 2. Comparison of age and biochemical parameters of the participants

Variables	Accept insulin Median (min-max)	Refusing insulin Median (min-max)	Total Median (min-max)	p
Age (year)	61.00 (36.00-84-00)	67.00 (45.00-83.00)	62.00 (36.00-84.00)	0.152
Monthly income (TL)	7500 (3000-20000)	6500 (3500-18000)	7000 (3000-20000)	0.917
Number of households	3.00 (1.00-7.00)	2.00 (1.00-6.00)	2.00 (1.00-7.00)	0.856
T2DM vintage(year)	13.00 (1.00-47.00)	15.00 (1.00-30.00)	15.00 (1.00-47.00)	0.329
BMI (kg/)	27.55 (19.27-35.91)	27.46 (20.66-41.77)	27.50 (19.27-41.77)	0.891
Fasting blood glucose (mg/dl)	158.00 (72.00-551.00	186.00 (75.00-496.00)	164.00 (72.00-551.00)	*<0.001*
HbA1c (%)	8.0 (5.80-13.50)	10.90 (7.80-17.00)	9.60 (5.80-17.00)	*<0.001*
Triglyceride (mg/dl)	152.00 (11.00-1206.00)	153.00 (62.00-594.00)	152.00 (11.00-1206.00)	0.101
LDL (mg/dl)	114.00 (37.00-203.00)	110.00 (24.00-197.00)	110.50 (24.00-203.00)	0.312
HDL (mg/dl)	48.50 (19.20-81.00)	48.00 (22.00-71.00)	48.00 (19.20-81.00)	0.419
Total cholesterol (mg/dl)	190.00 (93.00-376.00)	194.50 (95.00-310.00)	190.50 (93.00-376.00)	0.259

TL: Turkish lira; BMI: Body mass index; LDL: Low-density lipoprotein; HDL: High-density lipoprotein

Table 3. Comparison of the scale scores of the participants

Scales	Accept insulin Median (min-max)	Refusing insulin Median (min-max)	Total Median (min-max)	p
MMAS-8	8.00 (1.00-8.00)	7.00 (1.00-8.00)	8.00 (1.00-8.00)	0.119
Beck depression inventory	17.00 (4.00-41.00)	21.00 (8.00-36.00)	18.50 (4.00-41.00)	*0.002*
Beck anxiety inventory	9.00 (1.00-25.00)	17.00 (4.00-51.00)	13.00)1.00-51.00)	*<0.001*
D-FISQ	15.00 (15.00-30.00)	30.00 (15.00-60.00)	15.00 (15.00-60.00)	*<0.001*

MMAS-8: modified morisky adherence scale of 8 items; **D-FISQ**: Diabetes Fear of Self-injecting and Self-testing Questionnaire

Table 4. Spearman correlation analysis between treatment adherence scale and some variables

Variables	Accept insulin	Refusing insulin
	MMAS-8	MMAS-8
Beck depression inventory	r=-0.060	r=-0.266
	p= 0.600	p= ***0.017***
D-FISQ	r=-0.224	r=-0.309
	p= ***0.045***	p= ***0.005***
Beck anxiety inventory	r=-0.105	r=-0.137
	p= 0.356	p= 0.227
Age	r= 0.078	r=-0.152
	p= 0.491	p= 0.179
Monthly income (TL)	r=-0.091	r= 0.085
	p= 0.420	p= 0.456
Number of households	r -0.168	r=-0.007
	p= 0.136	p= 0.953
T2DM vintage (year)	r=-0.031	r=-0.193
	p= 0.783	p= 0.087
HbA1c	r=-0.347	r= 0.006
	p= ***0.002***	p= 0.961

MMAS-8: modified morisky adherence scale of 8 items; **D-FISQ**: Diabetes Fear of Self-injecting and Self-testing Questionnaire

DISCUSSION

The current study focused on the psychosocial factors affecting the acceptance and refusal of insulin therapy in patients who were under follow-up and treatment for T2DM. Fasting plasma glucose and HbA1c values were found to be higher in patients who refused insulin treatment. In addition, patients who refused insulin therapy had a history of more hospitalizations in the last 1 year. Although oral hypoglycemic agents may initially lower blood glucose and HbA1c levels, they are not as effective as insulin therapy in the long term [15]. Therefore, it is expected that the plasma glucose and HbA1c levels of patients who received insulin therapy would be lower than those of patients who refused insulin therapy. Prediabetes and diabetes are known to be associated with increased hospitalization rates during long-term follow-up. Previous studies have shown that among individuals with diabetes, those with poor glycemic control had a 39% higher hospitalization rate than those with good glycemic control [16]. The current findings support that patients who refuse insulin therapy have poor glycemic control and higher hospitalization rates.

The present study showed that both depression and anxiety scores were higher in diabetic individuals who refused insulin treatment. Previous literature has reported that depression and fear negatively affect adherence to insulin therapy [17]. Another study reported emotional or psychological problems of patients as the reason for delaying insulin treatment [15]. Yen et al. [18] reported that diabetic individuals with depression had difficulties in initiation and adherence to insulin therapy. Depression is associated with decreased adherence to medical regimens in patients with chronic diseases. The current study focused on insulin treatment acceptance in individuals without depression and anxiety. Makine et al. reported that patients with high depression scores were less accepting of insulin treatment than those with low depression scores [19]. Wijk et al. [20] showed that an intervention program for factors such as depression, anxiety and general stress increased insulin treatment acceptance and adherence to treatment. Considering the current study data and previous literature, we recommend that depression and anxiety should be evaluated before starting insulin therapy in individuals without a diagnosis of depression and anxiety.

Fear of pain and needles, concerns about the side effects of insulin and the complexity of administering insulin are some of the biggest barriers to starting insulin. The current study showed that patients' fear of self-injection and testing was another reason for refusing insulin treatment. Previous literature has also shown an association between fear of injections and delay and nonadherence to insulin therapy [15,17]. It is expected that the pain caused by insulin injection therapy and its negative impact

on the patient's comfort of life would be associated with treatment refusal and non-adherence. We believe that this problem can be solved with the development of alternative insulin treatment methods.

In the present study, depression and fear of self-injection and testing scale scores were found to be statistically significantly negatively correlated with treatment adherence scale scores. Both depression and fear of injection are known to be associated with poorer treatment adherence. Previous studies have shown that psychological intervention increases diabetes self-management [21]. There are not enough studies in the literature on the effect of supportive treatment on individuals' fear of injection, depression and anxiety. Current findings and literature data are limited to explain the effect of psychological support therapy on individuals' depression, anxiety and fear. We believe that individuals' depression, anxiety and fears should be reduced in order to increase acceptance and compliance with insulin therapy. We recommend that future research should focus on the effect of supportive therapies on depression, anxiety and fear in diabetic individuals. Improvement in depression, anxiety and fear levels were thought to be important in diabetes control.

This study has some limitations, firstly, since it is a cross-sectional and single-center study, patients may not fully reflect the general population. Initiation of insulin may be affected by the culture and health insurance system of the country. Therefore, there are limitations in generalizing these findings to other countries. Strengths of this study include the calculation of the sample size and the investigation of psychological factors in insulin acceptance and refusal with adequate sample size. Another strength is that participants' psychological characteristics such as depression, anxiety and fear were assessed using quantitative scales.

CONCLUSION

The present study showed that depressive and anxiety moods of the individuals caused insulin treatment refusal. In addition, fear of injection was another factor causing insulin treatment refusal. Depression and anxiety were also found to negatively affect adherence to treatment. To increase the acceptance and efficacy of insulin therapy, we recommend psychological evaluation of patients who are offered insulin therapy. In future studies, we recommend investigating the effect of psychotherapeutic interventions to reduce depression and anxiety on insulin refusal and adherence to treatment.

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